

# **Triathlon<sup>®</sup> Tritanium<sup>®</sup> Total Knee System** Clinical evidence

Volume 2.5



## Executive summary

Cemented total knee arthroplasty (TKA) has been the gold standard in knee arthroplasty for many years. Despite its long history, it is not the ideal solution for all TKA candidates.<sup>1,2,34,38</sup> As patients requiring TKA have become younger,<sup>2,10,34</sup> higher demand and heavier,<sup>10,23,36,38,40</sup> a more durable bone-implant interface is needed to withstand the added mechanical stress to help decrease component loosening and help improve implant survivorship in this challenging patient demographic.<sup>11,38</sup> Cementless TKA fixation is gaining a resurgence in popularity due to its potential to preserve bone stock, avoid cement debris and achieve lasting biologic fixation of the implant to the bone.<sup>2</sup> In this clinical and economic summary, we will review the clinical outcomes, implant fixation and cost-effectiveness of the Triathlon Tritanium Total Knee System.

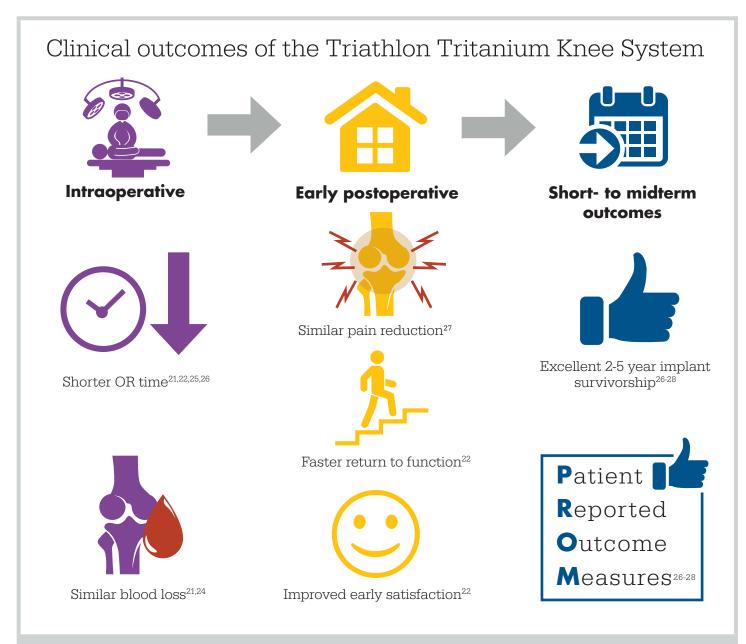


Figure 1. Favorable intraoperative, early postoperative and short- to midterm outcomes with Triathlon Tritanium Total Knee System compared to cemented TKA

Introduction4
Intraoperative and early postoperative clinical outcomes5
Favorable early- to midterm clinical outcomes and survivorship <b>7</b>
Encouraging outcomes in challenging patient demographics 10
Radiostereometric analysis (RSA) 12
Value of cementless TKA 14
Summary 14
References

#### Introduction

The introduction of bone cement (polymethylmethacrylate, PMMA) in the 1960s played a significant role in the success of joint replacement procedures.<sup>3</sup> Cemented stem fixation in total hip arthroplasty (THA) became widely used in young and old patients and for both primary and revision procedures. Inconsistent results were seen with different implant designs and cement techniques that were more common than previously expected.<sup>4</sup> Cementless THA has grown in popularity in many parts of the world<sup>7-9</sup> due to its relative ease and efficiency in implantation<sup>6</sup> and for meeting the need for biologic fixation to decrease aseptic loosening.<sup>5</sup>

The need for TKA in younger, heavier and more active adult patients has been steadily increasing over the years.<sup>10</sup> Due to a higher risk of revision seen in this challenging group of patients,<sup>11</sup> an implant design that allows for initial biologic fixation to avoid aseptic loosening and provide long-term implant survivorship,<sup>12</sup> as previously seen with cementless THA, may help address the changing TKA patient demographic.<sup>13</sup>

The failure of early generations of cementless TKA implant designs, while all shown to be correctable, has led to the limited acceptance of this fixation method.<sup>14,15</sup> However, there is a renewed interest in cementless TKA with improvements in cementless technology and the availability of new biomaterials to help promote biologic fixation for better implant longevity.<sup>14</sup> The American Academy of Orthopaedic Surgeons (AAOS) evidence-based clinical practice guideline found strong evidence supporting the use of cemented or cementless tibial component fixation due to similar functional outcomes and rates of complication and reoperation.<sup>26</sup> In its 2020 annual report, the National Joint Registry in the U.K. supports the long-term outcome of cementless femoral components.<sup>7</sup> The American Joint Replacement Registry (AJRR) in their 2020 annual report specified the use of cementless fixation in primary TKA among males <65 years old showed slight favorability in cumulative percent revision, which reached statistical significance, but does not account for other potential confounders at six-year follow-up.9



Advantages of cementless TKA compared to cemented TKA that have been shown in the literature include:

- 1. shorter surgical times  $^{21,22,25,26}$
- 2. comparable blood  $loss^{21,24}$
- 3. comparable pain relief<sup>21,27</sup>
- 4. improved patient satisfaction  $^{22}$
- 5. improved clinical outcomes  $^{22,24}$
- $\begin{array}{ll} \text{6. potential long-term implant survivorship in} \\ \text{challenging patient demographics}^{34,35,39,40,41,44} \text{ and} \\ \text{potential cost-savings}^{57} \end{array}$

Triathlon Tritanium combines the kinematics of Triathlon with the latest in highly porous biologic fixation technology. The innovation behind the Tritanium Tibial Baseplate and Metal-Backed Patella components are enabled by Stryker's proprietary AMagine Additive Manufacturing and SOMA, Stryker Orthopaedic Modeling Analytics technology. The Triathlon Tritanium cementless TKA implant was introduced with otherwise similar design features to its cemented counterpart, which has demonstrated over 10 years of good track record.<sup>12</sup>

Clinical outcomes following TKA are critical in assessing an implant's performance. The introduction of highly porous surfaces that promote biologic fixation has shown encouraging results and has led to a renewed interest in cementless fixation.<sup>12</sup> However, concerns of blood loss, prolonged or persistent pain, patient satisfaction and limited long-term survivorship and outcomes data with some cementless TKA implant designs persist.<sup>12</sup>

Compared to the cemented Triathlon TKA system, the Triathlon Tritanium TKA shows favorable intraoperative outcomes (significantly shorter tourniquet<sup>25</sup> and operating room (OR) time<sup>21,22,25,56</sup> and similar blood loss<sup>21,24</sup>) and early postoperative outcomes (similar pain reduction,<sup>27</sup> faster return to function<sup>22</sup> and improved patient satisfaction<sup>22</sup>). Encouraging early- and midterm implant survivorship and good clinical and radiographic outcomes have also been reported in clinical studies.<sup>26-28</sup>



### Intraoperative and early postoperative clinical outcomes

In a prospective randomized controlled trial, Nam and colleagues compared groups that were implanted with a cemented Triathlon cruciate retaining (CR) TKA or a cementless peri-apatite (PA) beaded Triathlon femoral component and Tritanium tibial baseplate; the patella was not resurfaced in either cohort. All patients were permitted to be full weight bearing, start range of motion as tolerated and ambulated on the day of surgery. One-hundred forty-seven (67 cemented and 80 cementless) patients were followed for two years.<sup>21</sup> No significant difference was noted in estimated blood loss despite pneumatic tourniquet used only in the cemented cohort.<sup>21</sup> Total operative time was significantly shorter in the cementless cohort compared to the cemented cohort **(Table 1)**.

 Table 1: Comparison of intraoperative and perioperative variables between cemented and cementless cohorts<sup>21</sup>

	Cemented (n=65)	Cementless (n=76)	p-value
Operative time (min)	93.7 ± 16.7	$82.1 \pm 16.6$	0.001
Estimated blood loss (mL)	185.2 ± 134.9	183.3 ± 146.7	0.9
Preoperative hemoglobin (g/dL)	$13.6 \pm 1.3$	$14.2 \pm 1.4$	0.01
Postoperative hemoglobin (g/dL)	$11.1 \pm 1.2$	$11.6 \pm 1.4$	0.03
Change in hemoglobin (g/dL)	$-2.5 \pm 0.9$	$-2.6 \pm 1.4$	0.5

There was no difference in postoperative pain at four to six weeks and at two-year follow-up and no difference in Oxford Knee Score (OKS), Knee Society Score (KSS - pain and function) or Forgotten Joint Score (FJS) between both cohorts at all postoperative time points.<sup>21</sup> One revision due to periprosthetic infection was reported in the cemented cohort, and no revisions were reported in the cementless cohort. In addition, radiographic review showed no evidence of component loosening or subsidence in either group.<sup>21</sup>

A faster return to function and improved early patient satisfaction was seen by Sharpe and colleagues when comparing cementless versus cemented TKA in a prospective non-randomized multicenter study.<sup>22</sup> Patients in the cementless cohort (373 knees in 319 patients) received the Triathlon Tritanium Tibial Baseplate and Metal-Backed Patella with Triathlon PA femoral component while the comparator (146 knees in 133 patients) received the cemented Triathlon Total Knee System.<sup>22</sup> OKS, new American Knee Society Score (KSS-2011) and Short Form 12 (SF-12) were collected through the one-year postoperative follow-up. Their findings, as presented in Figures 2 and 3, show that while cementless and cemented fixation provided similar positive outcomes at one year, cementless TKA may provide faster return to function, corresponding to increased patient satisfaction in the early postoperative period.<sup>22</sup>

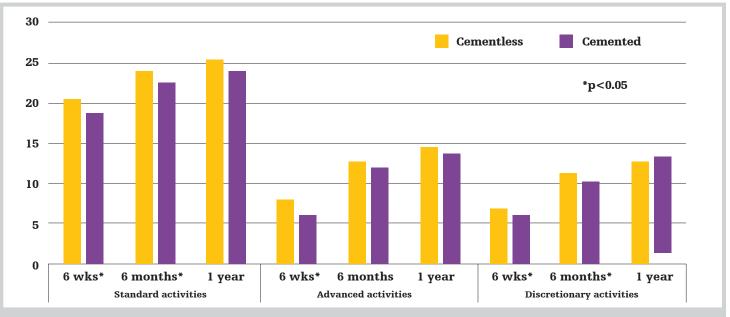
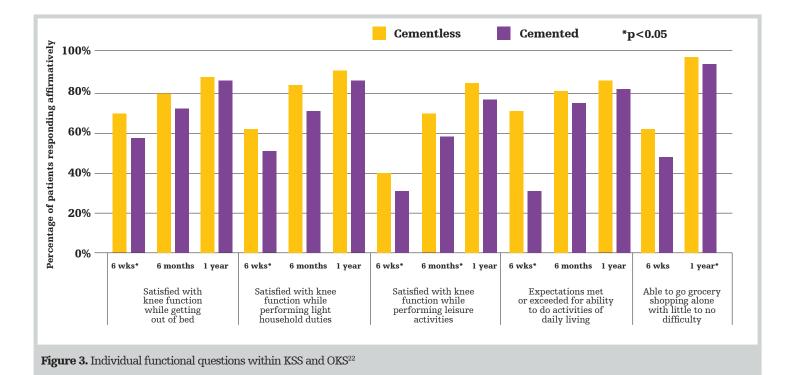


Figure 2. KSS-2011 function subscales<sup>22</sup>





Improved early clinical outcomes, shorter tourniquet time with cementless TKA and similar blood loss between cementless and cemented TKA was reported by Miller et al. in a retrospective matched case-control study of 400 primary TKAs, where 200 patients implanted with a Triathlon PA beaded femoral component, posterior stabilized (PS) Triathlon Tritanium Tibial Baseplate and a cementless patellar component were compared to a matched cohort of 200 patients from a prospective total joint registry implanted with a cemented TKA component of the same design.<sup>24</sup> Cohorts were matched by age, body mass index (BMI) and preoperative KSS. The mean follow-up in the cementless group was 2.4 years (range, 2-3.5 years) and in the cemented group was 5.3 years (range, 2-10.9 years). Blood loss was not significantly different between cohorts (355 ml, SD=276.1 versus 557 ml, SD=409.1, p=0.27).<sup>24</sup> Patients in the cementless cohort showed better improvement in their clinical outcome scores at two years (Table 2).<sup>24</sup> A single case of aseptic tibial loosening was reported in the cementless group, while five cases of aseptic loosening were reported in the cemented group (0.5% vs 2.5% p=0.09).<sup>24</sup>

Table 2: Comparison of outcome scores in matched cementless vs. cemented TKA.<sup>24</sup>

Outcome score	Cemented TKA	Cementless TKA	p-value
KSS function score	$70.2 \pm 22.3$	$76.0 \pm 20.4$	.016
Change in function score	$26.04 \pm 26.6$	35.6 (±19.8)	.0014
KSS knee score	$91.6 \pm 9.8$	$94.1 \pm 6.1$	.0076
Change in knee score	$52.4 \pm 16.7$	$53.8 \pm 13.8$	.385

## Favorable early- to midterm clinical outcomes and survivorship

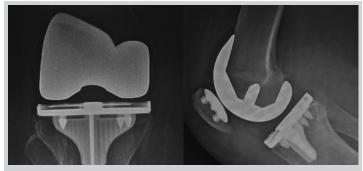
Since Triathlon Tritanium Tibial Baseplate was launched in 2013, favorable early- to midterm performance of this device is starting to be generated and published from multiple centers.

**Table 3:** Triathlon Tritanium Tibial Baseplate and Metal-<br/>Backed Patella (MBP) midterm survivorship

Reference
Cohen et al. <sup>25</sup>
Harwin et al. <sup>27</sup>
Harwin et al.62
Grau et al.61
Tarazi et al. <sup>28</sup>
Restrepo et al.41
Bhowmik-Stoker et al. <sup>69</sup>

 $^{\mathrm{a}}\mathrm{Tibial}$  baseplate,  $^{\mathrm{b}}\mathrm{MBP},$   $^{\mathrm{c}}\mathrm{Tibial}$  baseplate and MBP

In a large series comparing two cementless implants, PA beaded (805 patients) and highly porous titaniumcoated tibial and patella components (219 patients), Harwin et al. compared survivorship, KSS, range of motion (ROM), complications and radiographic findings between the two groups and found that at a mean follow-up of 4.4 years (range, 2-9 years), all-cause implant survivorship was 99.5% for both groups.<sup>27</sup> No significant differences were noted in pain, function or ROM for either group. Complication rate and number of revisions were also similar in both cohorts.<sup>27</sup>



**Figure 4.** Anteroposterior and lateral view of the knee after total knee arthroplasty with the Triathlon Tritanium Cementless Total Knee System

Promising clinical outcomes at five years were reported by Tarazi and colleagues.<sup>28</sup> They reviewed a prospectively collected database and identified 228 patients who underwent TKA with Triathlon Tritanium baseplate implants. These patients were evaluated clinically at a minimum of five years. Implant survivorship of this cohort of patients was 99.5%. Improvements in both Knee Society pain and function scores as well as improvements in range of motion were reported.<sup>28</sup>

Similar findings were demonstrated by Restrepo et al., who collected data on 296 TKA cases using Triathlon Tritanium.<sup>41</sup> They reported a 99.2% survivorship for aseptic loosening of the 3D-printed tibial component at a minimum five years follow-up. Patients also reported a statistically significant improvement in their Knee injury and Osteoarthritis Outcome Score (KOOS JR) and the physical and mental health component scores of the Veterans Rand (VR)/12 Item Short-Form Health Survey (SF-12).<sup>41</sup>

Regardless of implant fixation methods, complications involving the patella still account for nearly 10% of TKA failures, and the metal-backed patella design has historically shown unacceptably high revision rates.<sup>61,62</sup> Two separate studies evaluated the survivorship, clinical and radiographic outcomes of the Triathlon Tritanium MBP. A single high-volume surgeon reported on 261



patients who underwent cementless TKA. After a mean follow up of 4.5 years, he reported high rates of patellar implant survivorship (98%) and low complication rates.<sup>62</sup> Grau and colleagues identified 388 cementless MBP TKA cases with minimum two years follow-up and 80 with minimum five years follow-up from their hospital-based registry. Using the Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System, they demonstrated biologic fixation of the patellar component present in all except one case at two years (99.6%) and at five years (97.7%).<sup>61</sup> No component was revised for aseptic loosening.<sup>61</sup>

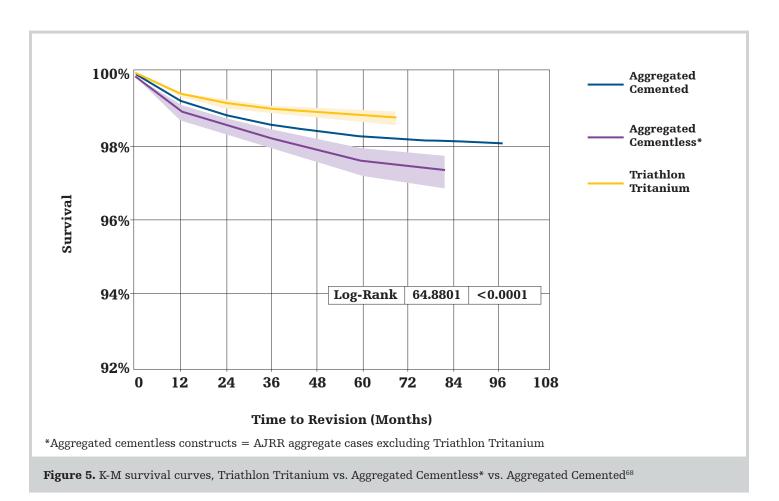
National registry data provides an independent perspective and valuable real-world evidence on the performance of orthopaedic devices. The strength of registries lies in the large volume of implants captured from diverse healthcare settings that include community and academic hospitals, ambulatory surgery centers and private practice settings.<sup>70</sup>

The mid-term performance of the Triathlon Tritanium tibial baseplate<sup>68</sup> and Metal-backed patella (MBP)<sup>69</sup> was recently investigated using data from the American Joint Replacement Registry (AJRR).

Triathlon Tritanium tibial baseplate cases (N=37,105) submitted to AJRR from November 6, 2012 to December 4, 2020 from 428 institutions were identified. These cases were compared to all other "Aggregated Cementless" as well as "Aggregated Cemented" knee cases. Available data from the Centers for Medicare and Medicaid Services (CMS) were merged with AJRR data to generate Kaplan Meier (K-M) survivorship and patient time incidence rate (PTIR) per 1000 years.<sup>68</sup> The Social Security Death Index was cross referenced. Cases are noted as survived unless otherwise reported to AJRR.<sup>68</sup> Implant survivorship Table 4: Summary of Triathlon Tritanium tibial baseplate survivorship by K-M and PTIR  $estimates^{68}$ 

Group	Total implanted (N)	K-M Survivorship (CI)	PTIR per 1000 years (CI)
Triathlon Tritanium	37,105	98.9 (98.7, 99)	3.07 (2.74, 3.43)
Aggregate cementless	9,505	97.6 (97.3, 98)	4.89 (4.22, 5.67)
Aggregate cemented	725,417	98.3 (98.3, 98.3)	3.72 (3.65, 3.79)

free of revision was 98.9% CI [98.7%, 99.0%], with the Triathlon Tritanium baseplate, 97.6% CI [97.3%, 98.0%], in the aggregate cementless group, and 98.3% CI [98.3%, 98.3%] in the cemented knee group at 60-month follow-up (p<0.001). PTIR was 3.07 (2.74, 3.43), 4.89 (4.22, 5.67), and 3.72 (3.65, 3.79) for 3D TKA, aggregate cementless and cemented knee groups. This corresponds to a revision rate of 0.31% per year, 0.49% per year, and 0.37% per year for the 3D TKA, aggregate cementless, and cemented knee groups, respectively (p<0.001). [Table 4]<sup>68</sup>



This work is the first midterm report of the 3D TKA from a large national registry. Results show that Triathlon Tritanium tibial baseplates had slighlty favorable PROMS and survivorship at 5 years over aggregate cementless, and cemented knees implanted at the same institutions in the same period.<sup>68</sup> The 3D TKA group had 98.9% survivorship at 60 month-follow up and a PTIR of 0.31% revision/year, which was significantly better than the matched groups. More critically, confidence intervals for the 3D TKA group did not overlap with other groups indicating a clear distinction in results. Cementless knee groups also had no clinical differences in reasons for revision related to fixation such as aseptic loosening.<sup>68</sup>

A similar analysis was performed on the Triathlon Tritanium MBP using data from AJRR merged with CMS. 28,257 cases from 656 surgeons across 369 sites were identified and included in the analysis. MBP survivorship at a mean follow-up of 2.6 years (longest follow-up of 6 years) is summarized in Table 5. **Table 5:** Summary of Triathlon Tritanium MBP survivorship by K-M and PTIR  $\mathsf{estimates}^{69}$ 

Device	Total	K-M	PTIR per 100
	implanted (N)	Survivorship (CI)	years (CI)
Triathlon Tritanium MBP	28,257	98.97 (98.8, 99.12)	0.29 (0.26, 0.33)

The design of the Triathlon MBP was developed to address past failures of metal-polyethylene dissociation by enhancing the bond between the two components.<sup>70</sup> The architecture on the back side, combined with a direct compression molding process, is designed to minimize the potential for dissociation.<sup>71</sup>

This analysis based on AJRR and CMS data on the first 3D-printed metal-backed patellar component is encouraging, as it suggests excellent survivorship at mean 2.6 year and a maximum 6-year follow-up in a large patient cohort.<sup>69</sup>

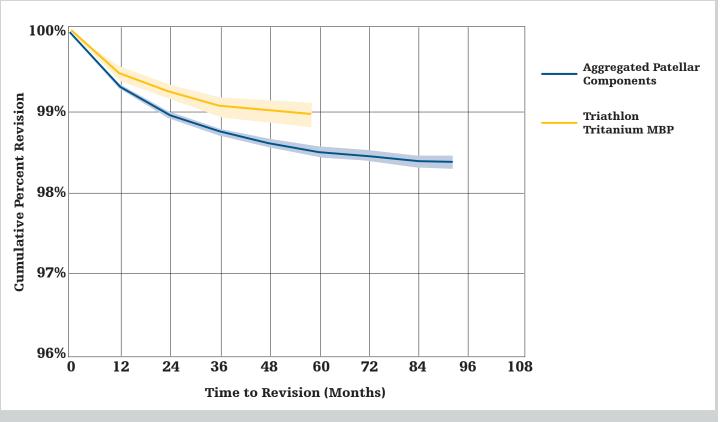


Figure 6. Kaplan-Meier survival curve for the Triathlon MB Patella compared to all other AJRR Patellar components in primary TKA cases.<sup>69</sup>

## **Encouraging outcomes in challenging patient demographics**

#### Young and active adult patients

Age can be a major factor that affects the outcome of primary TKA. Various national joint replacement registries have shown that the revision rate increases with decreasing age.<sup>7,8,30</sup> Aseptic loosening and instability were identified as reasons for revision in younger patients due to their higher activity level leading to greater stress on the implant.<sup>32</sup> One study reported 4.7x higher risk of aseptic revision within one year of TKA in patients less than 50 years of age.<sup>33</sup>

Mont and colleagues reported 100% survivorship in patients <50 years of age undergoing cementless primary TKA at a single high-volume institution. Twenty-nine patients (31 knees) with a mean age of 45 years (range, 34-49 years) received a PA beaded femoral component (PS) and cobalt chrome (CoCr) tibial baseplate or a Triathlon Tritanium Tibial Baseplate when it became available; patellae were resurfaced.<sup>34</sup> At a mean four-year follow-up (range, 2-6 years), no failures or revision surgeries were performed and no radiographic evidence of component loosening or progressive radiolucency was reported.<sup>34</sup> Patients also demonstrated excellent functional outcome scores and ROM.<sup>34</sup>

Triathlon Tritanium TKA has demonstrated excellent survivorship, functional outcomes and satisfaction in both young<sup>34</sup> and elderly<sup>35</sup> adult patients. This versatility should help the orthopaedic surgeon address some of the challenges that have been identified with both age groups.

#### Patients with BMI 30-40

Obesity affects about 35% of the U.S. population and has been steadily increasing over the years.<sup>36</sup> The increased prevalence of obesity has been linked to the rapidly increasing demand for joint arthroplasty procedures, especially TKA.<sup>37</sup> In 1995, 42% of patients who underwent TKA were considered obese, and in 2005, this number increased to 60%.<sup>36</sup> This presents a challenge, as TKA in the morbidly obese has been associated with greater perioperative complications.<sup>36</sup>

In a study of over 5000 primary TKAs implanted using cemented components, patients with BMI  $\geq 35$  kg/m<sup>2</sup> were found to have an almost two times greater risk for aseptic tibial component failure.<sup>38</sup> Cemented TKAs also showed an increase in failure rates due to aseptic loosening in obese patients despite well-aligned knees.<sup>38</sup> The following studies offer data that demonstrate cementless TKA may be a good option in the obese patient.

Sharpe and colleagues compared outcomes and implant survivorship of cementless TKA between two groups of patients stratified by BMI in a multicenter prospective study. Cementless TKA patients were stratified based on BMI, < 30 kg/m<sup>2</sup> (non-obese) or BMI 30 to < 40 kg/m<sup>2</sup> (obese). OKS, KSS-2011, SF-12 and SF-6D transformed health utility scores were collected through two years.<sup>39</sup> An interesting finding was that in the obese cohort, patients reported higher satisfaction scores at the sixth postoperative week and experienced a significant improvement in function as early as six

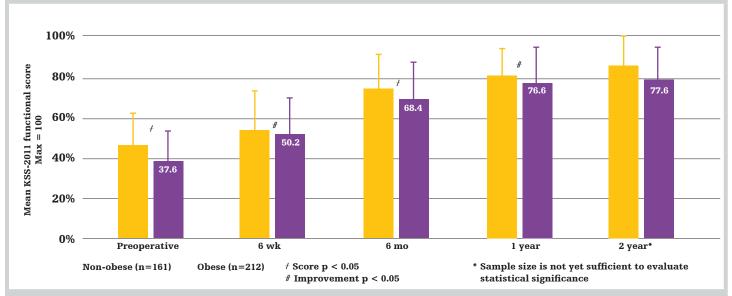
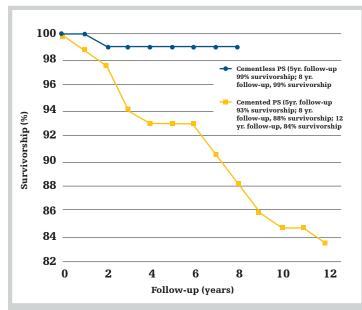


Figure 7. Cementless cohort KSS-2011 functional score by BMI

weeks postoperative, which was sustained through two years of follow-up. No statistically significant difference in adverse events or implant survivorship were seen between the cemented and cementless groups.<sup>39</sup>

In a retrospective study comparing cemented versus cementless primary TKA with a PS design in morbidly obese (BMI  $\geq$ 40) patients, Sinicrope and colleagues extracted demographic, clinical, surgical, radiographic, postoperative complications and survivorship in 193 patients. At a minimum follow-up of five years, five failures requiring revisions were reported in the cementless group including one for aseptic tibial loosening (0.9%), while 22 failures requiring revisions were reported in the cemented group, including 16 cases of aseptic loosening (18.8%).<sup>40</sup> A statistically significant difference in survivorship (p=0.02)was noted with aseptic loosening as the endpoint; 99.1% implant survivorship in the cementless group versus 88.2% in the cemented cohort at eight years (Figure 8). These results led the authors to conclude that "the use of cementless TKA in morbidly obese patients with the potential of durable long-term biologic fixation and improved survivorship appears to be a promising alternative to mechanical cement fixation."40



**Figure 8.** Kaplan-Meier survival curve of primary TKA in morbidly obese patients with aseptic loosening as the endpoint.<sup>40</sup>

#### Triathlon Tritanium clinical evidence

Harwin, et al. were able to show no significant difference in component survivorship when comparing patients of varying BMI (less than 30 kg, 30-40 kg/  $m^2$ , 40-50 kg/ $m^2$ ). They reported 99% survivorship (CI:0.997 to 0.983) at mean 27 months follow-up in 708 cementless TKAs using Triathlon Tritanium.<sup>41</sup>

#### Patients with rheumatoid arthritis

Rheumatoid arthritis (RA) is a systemic inflammatory disease that is characterized by chronic inflammation and progressive deterioration of joint function resulting in pain and disability.<sup>42</sup> In 2005, RA was estimated to affect 1.3 million adults in the U.S.<sup>43</sup> TKA is a treatment option in patients with RA but can be challenging due to higher incidence of poor bone quality, synovitis and disuse muscular atrophy. In this subset of patients, cemented TKA is the usual recommended approach, but only a limited number of studies have evaluated the safety and efficacy of cementless TKA in patients with RA.

One hundred twenty-two patients (126 TKAs) diagnosed with RA were enrolled by Patel et al. in a study to investigate implant survivorship and clinical outcomes. Patients were not excluded because of subjective view of poor bone stock. All patients were implanted with a cementless PA beaded femoral component and CoCr tibial baseplate. Patella resurfacing was done on all patients using PA-coated patellae. From June 2013 and onwards, a Triathlon Tritanium Tibial Baseplate was used, and patellae were resurfaced with a highly porous-coated, metalbacked prosthesis.<sup>44</sup> At a mean follow-up of four years (range, 2-8 years), excellent implant survivorship was reported (99.2%) in patients with RA. Clinical and patient-reported outcomes at final follow-up were excellent with no surgical complications reported. Radiographic review revealed no radiolucency or loosening, although one patient was revised due to tibial baseplate subsidence. This study has demonstrated that cementless TKA may be an option for patients with RA.44

## Radiostereometric analysis (RSA)

Radiostereometric analysis (RSA) is an accurate 3D imaging technique that uses two simultaneous calibrated radiographs to precisely monitor changes in implant position over time. Implant migration over the first two postoperative years has been shown to be predictive of aseptic loosening and migration that is less than 0.2 mm in the second-year postoperative period indicates stable fixation.<sup>45</sup> RSA allows prediction of loosening with small sample sizes and is being advocated as an important tool for introducing new and innovative implants to the orthopaedic market.<sup>45</sup>



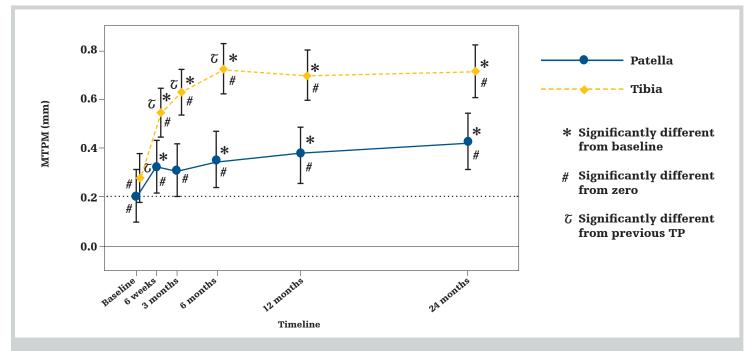
Figure 9. Two simultaneous calibrated radiographs are used to precisely monitor changes in implant position over time

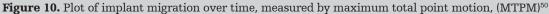
#### Initial stability

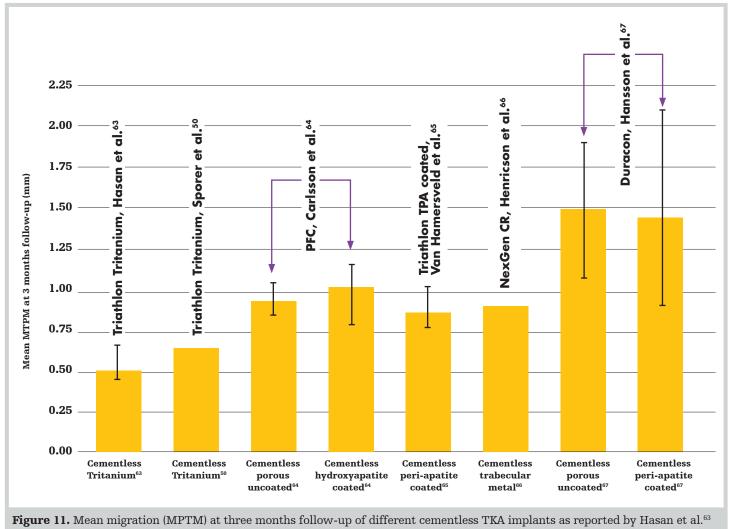
Given the importance of stable primary fixation,<sup>46</sup> the keel and four bullet cruciform pegs on the Tritanium baseplate were designed to reduce micromotion and liftoff.<sup>47-48</sup> The SOMA database of bone morphology was used to optimize the depth and placement of the pegs.<sup>49</sup>



Using RSA technology, Sporer and colleagues sought to investigate the press-fit fixation of Triathlon Tritanium Tibia and Metal-Backed Patella to the underlying bone. Twenty-nine patients were prospectively enrolled and RSA images collected at the immediate postoperative, at six weeks, and at three-, six-, 12- and 24-month follow-up visits. Most component migration was observed over the first six postoperative weeks, after which no significant migration between the 12- and 24-month time points was observed. This demonstrates the biphasic migration pattern that has been reported for cementless components, characterized by a high initial migration followed by stabilization or a plateau of migration<sup>50</sup> (Figure 10). This early migration pattern suggests the patella and tibia achieve fixation through the porous titanium surface.







The error bars represent 95% confidence intervals as reported. $^{63}$ 

A similar migration pattern was reported by Hasan and colleagues. In a randomized controlled study, they assigned patients to receive either cementless Triathlon Tritanium or Triathlon CR cemented and compared migration patterns over two years through RSA. They noted a higher migration in the cementless cohort due to a higher initial migration after which stabilization was observed.<sup>63</sup> The main direction of migration was subsidence in the first three months. This is consistent with other RSA studies

using cementless implants.<sup>50,63-67</sup> When compared with other cementless designs, Triathlon Tritanium cementless TKA shows promising results as the initial migration seems to be lower **(Figure 11)**.<sup>63</sup>

This pattern of component migration is consistent with other longer-term RSA studies showing that stabilization of uncemented tibial components can be achieved after high initial migration.<sup>46,51,52</sup>

## Value of cementless TKA

As the volume of total joint replacement procedures continue to increase, the costs associated with this surgical procedure continues to be an important topic of discussion and research. While implant cost has long been a focus of the expense associated with joint arthroplasty procedures,<sup>53</sup> other factors such as hospital length of stay and operating room costs have been identified to contribute significantly to the total cost of these procedures. As data continue to be generated, available evidence demonstrates that cementless TKA can be a potential cost-beneficial alternative to cemented TKA.

Significantly shorter OR time consistently seen with cementless TKA **(Table 6)** can be a potential factor affecting the cost of the procedure, considering that each minute of OR time in the U.S. is estimated to be worth \$62 (excluding surgeon and anesthesia time)<sup>54</sup> and a median of £16 per minute (range, £12-£20 per minute) in the UK.<sup>55</sup> Differences in OR time between cemented and cementless TKA was used for cost comparison of these procedures by Lawrie and colleagues.<sup>57</sup> When looking at cost variables including

OR time, cement, cement accessories and implants benchmarked against data from Nam et al. for OR time, using institutional and market data for costs of cement, accessories and implants, they found that the actual cost of cementless and cemented TKA are similar.<sup>57</sup>

The use of antibiotic-impregnated bone cement is not approved for prophylactic use in primary total joint procedures. Literature suggests that "an increasing number of surgeons in the U.S. have adopted the practice of routine addition of low-dose antibiotic to cement for use in primary knee arthroplasty."<sup>58,59</sup> The use of antibiotic bone cement potentially increases the cost of cemented TKA.<sup>29,31</sup>

Although the cost of a cementless prosthesis is traditionally greater than that of a cemented implant, other perioperative factors such as the cost of cement, other equipment/accessories (vacuum mixer, cement injection kit) and OR times<sup>60</sup> as well as short-term and longer-term outcomes, should be considered when evaluating cementless TKA prostheses.

Table 6: OR time significantly shorter in cementless compared to cemented TKA

Study	Cemented TKA (minutes)	Cementless TKA (minutes)	P value
Nam et al <sup>21</sup>	$93.7 \pm 16.7$	$82.1 \pm 16.6$	0.001
Cohen et al. <sup>25</sup>	$45.6 \pm 7.2$	$40.8 \pm 6.0$	0.0006
Chen et al. <sup>56</sup>	$80.0 \pm 34.3$	$62.3 \pm 17.4$	NR
Sharpe et al. <sup>22</sup>	$83.4 \pm 24.5$	$60.5 \pm 19.4$	<0.0001

NR – Not reported

#### Summary

The optimal fixation method in TKA continues to be debated. The collection of studies presented here on the additive manufactured Triathlon Tritanium Knee System using new biomaterials that can help promote initial biologic fixation demonstrate encouraging perioperative outcomes (comparable pain score<sup>27</sup> and blood loss,<sup>21,24</sup> shorter OR<sup>21,22,25,56</sup> and tourniquet time<sup>12,24</sup>), favorable short- to midterm implant survivorship<sup>25-28</sup> similar to its cemented counterpart and may be a good option for patients requiring TKA, especially younger, heavier and more active adult patients.

The cost of cementless TKA implants continues to be an important consideration, but data from various studies are starting to show the value of shorter operating room times, fewer supplies and equipment needed and better patient outcomes.

Available publications are showing the clinical and economic benefits of the Triathlon Tritanium TKA system. It offers surgeons the versatility to address the needs of a challenging subset of patients including young,<sup>34</sup> active and obese patients.<sup>39-41</sup>

Long-term data on implant survivorship is not yet available, but encouraging midterm survivorship and RSA data on the Triathlon Tritanium Baseplate and Metal-Backed Patella shows stable migration at two years consistent with biologic fixation of the uncemented components.<sup>50</sup>

#### References

- Jackson J.D., Pagnano M.W. (2012) Cement fixation for total knee arthroplasty. In: The Knee Joint. Springer, Paris. pp 759-764.
- 2. Dalury, DF. Cementless total knee arthroplasty. Bone Joint J 2016;98-B:867-73.
- Webb, JCJ and Spencer, RF. The role of polymethylmethacrylate bone cement in modern orthopaedic surgery. BJJ. VOL. 89-B, No. 7, JULY 2007.
- 4. Barrack, RL. Early Failure of Modern Cemented Stems. The Journal Of Arthroplasty. Vol. 15, No. 8, Aug. 2000.
- Lettich, T. et.al., Primary Total Hip Arthroplasty with an Uncemented Femoral Component: Two- to Seven-Year Results. The Journal of Arthroplasty Vol. 22 No. 7 Suppl. 3 2007.
- Fleischman, AN et.al. Reduced Incidence of Intraoperative Femur Fracture With a Second-Generation Tapered Wedge Stem. The Journal of Arthroplasty 32 (2017) 3457-3461.
- National Joint Registry for England, Wales and Northern Ireland and Isle of Man. 16th. Annual Report. 2020.
- 8. Australian Orthopaedic Association National Joint Replacement Registry: Annual Report, 2018. (Last accessed, Nov. 11, 2018).
- 9. American Joint Replacement Registry: Annual Report, 2020.
- Memtsoudis SG, Della Valle AG, Besculides MC, Gaber L, Laskin R. (2009) Trends in Demographics, Comorbidity Profiles, InHospital Complications and Mortality Associated with Primary Knee Arthroplasty. Journal of Arthroplasty, Jun; 24(4):51827.
- Schreurs, BW, Hannik, G. Total Joint Arthroplasty in Younger Patients: Heading for Trouble? The Lancet (2017), volume 389, Issue 10077, P1374-1375.
- Nam, D., et.al. Perioperative and Early Postoperative Comparison of a Modern Cemented and Cementless Total Knee Arthroplasty of the Same Design. The Journal of Arthroplasty 32 (2017) 2151-2155.
- Nilsson K G, Henricson A, Norgren B, Dalen T. Uncemented HA-coated implant is the optimum fixation for TKA in the young patient. Clin Orthop Relat Res 2006; 448: 129-39.

- Meneghini RM, Hanssen A. Cementless Fixation in Total Knee Arthroplasty: Past, Present, and Future. J Knee Surg. 2008; 21:307-314.
- Bayley JC, Scott RD, Ewald FC, Holmes GB Jr. Failure of the metal-backed patellar component after total knee replacement. J Bone Joint Surg Am. 1988 Jun; 70(5):668-74.
- Bircher, A. et.al. Contact Dermatitis. Allergic complications from orthopaedic joint implants: the role of delayed hypersensitivity to benzoyl peroxide in bone cement. Contact Dermatitis. 2011 August, 66, 20–26.
- Granchi D., Cenni E., Tigani D., Trisolino G., Baldini N., Giunti A. (2008). Sensitivity to implant materials in patients with total knee arthroplasties. Science Direct, 29, 1494-1500. doi:10.1016/j.biomaterials.2007.11.038.
- Vega, F. Aseptic loosening of a total knee prosthesis caused by delayed hypersensitivity to bone cement. Annals of Allergy, Asthma & Immunology.Volume 117, Issue 1, July 2016, Pages 89-91.
- Keene, R. et.al. Occupational Hazards to the Pregnant Orthopaedic Surgeon. J Bone Joint Surg Am. 2011;93:e141(1-5).
- Pacheco, Karin A. Allergy to Surgical Implants. The Journal of Allergy and Clinical Immunology: In Practice, Volume 3, Issue 5, 683 – 695.
- Nam D, Lawrie CM, Salih R, Nahhas CR, Barrack RL, Nunley RM. Cemented Versus Cementless Total Knee Arthroplasty of the Same Modern Design: A Prospective, Randomized Trial. J Bone Joint Surg Am. 2019 Jul 3;101(13):1185-1192. doi: 10.2106/JBJS.18.01162. PMID: 31274720; PMCID: PMC6641115.
- 22. Sharpe, K., Robinson, K., Cohen, R., Barnett TM., Rastogi, A., Masini, M. Does Implant Fixation Affect Early Return to Function Following Primary Total Knee Arthroplasty. ISTA 2018. London, UK.
- 23. Sinicrope BJ, Feher AW, Bhimani SJ, Smith LS, Harwin SF, Yakkanti MR, Malkani AL. Increased Survivorship of Cementless versus Cemented TKA in the Morbidly Obese. A Minimum 5-Year Follow-Up. J Arthroplasty. 2019 Feb;34(2):309-314. doi: 10.1016/j. arth.2018.10.016. Epub 2018 Oct 17. PMID: 30446183.

- Miller, AJ, et. al., Results of Cemented vs Cementless Primary Total Knee Arthroplasty Using the Same Implant Design. J Arthroplasty. 2018 Apr;33(4):1089-1093. doi: 10.1016/j.arth.2017.11.048. Epub 2017 Dec 2.
- Cohen et al. "Early Clinical Outcomes of a New Cementless Total Knee Arthroplasty Design. Orthopedics. 2018.
- American Academy of Orthopaedic Surgeons (AAOS). Surgical management of osteoarthritis of the knee. Evidence-based clinical practice guideline. 2015; https://www.aaos.org/globalassets/quality-andpractice-resources/surgical-management-knee/smoakcpg\_4.22.2016.pdf.
- Harwin, SF. et al. Outcomes of Newer Generation Cementless Total Knee Arthroplasty: Beaded Periapatite-Coated vs Highly Porous Titanium-Coated Implant. J Arthroplasty. 2017 Jul;32(7):2156-2160. doi: 10.1016/j.arth.2017.01.044. Epub 2017 Feb 3.
- Tarazi JM, Salem HS, Ehiorobo JO, Sodhi N, Mont MA, Harwin SF. Cementless Tritanium Baseplate Total Knee Arthroplasty: Survivorship and Outcomes at 5-Year Minimum Follow-Up. J Knee Surg. 2020 Sep;33(9):862-865. doi: 10.1055/s-0040-1712983. Epub 2020 Jun 19. PMID: 32559788.
- 29. King, J.D., et al. The Hidden Cost of Commercial Antibiotic-Loaded Bone Cement: A Systematic Review of Clinical Results and Cost Implications Following Total Knee Arthroplasty. The Journal of Arthroplasty 3392018) 3789-3792.
- Swedish Knee Arthroplasty Register. Annual Report 2017. http://www.myknee.se/en/. (Last accessed, Nov. 11, 2018).
- Sultan, AA et al. Routine use of commercial antibioticloaded bone cement in primary total joint arthroplasty: a critical analysis of the current evidence. ANN Transl Med 2019;7(4):73.
- 32. McCalden et al "Comparison of Outcomes and Survivorship Between Patients of Different Age Groups Following TKA." The Journal of Arthroplasty, Churchill Livingstone, 24 July 2013, www.sciencedirect.com/ science/article/pii/S0883540313004774.
- 33. Meehan, JP, et.al. Younger Age Is Associated with a Higher Risk of Early Periprosthetic Joint Infection and Aseptic Mechanical Failure After Total Knee Arthroplasty. J Bone Joint Surg Am. 2014; 96:529-35.
- 34. Mont MA, Gwam C, Newman JM, Chughtai M, Khlopas A, Ramkumar PN, Harwin SF. Outcomes of a newergeneration cementless total knee arthroplasty design in patients less than 50 years of age. Ann Transl Med 2017;5(Suppl 3):S24. doi: 10.21037/atm.2017.08.20.

- Newman, J. et.al. Cementless Total Knee Arthroplasty in Patients Older Than 75 Years. The Journal of Knee Surgery. Vol. 30 No. 9/2017, P930-934.
- Martin, JR, et.al. Morbid Obesity and Total Knee Arthroplasty: A Growing Problem. Journal of the American Academy of Orthopaedic Surgeons: March 2017 - Volume 25 - Issue 3 - p 188–194. doi: 10.5435/ JAAOS-D-15-00684.
- Derman, PB, Fabricant, PD, David, G. The Role of Overweight and Obesity in Relation to the More Rapid Growth of Total Knee Arthroplasty Volume Compared with Total Hip Arthroplasty Volume. J Bone Joint Surg Am. 2014 Jun 4;96(11):922-928. Epub 2014 Jun 4.
- Abdel, MA. Et.al. Increased aseptic tibial failures in patients with a BMI >/=35 and well-aligned total knee arthroplasties. J Arthroplasty, 30 (2015), pp. 2181-2184.
- Sharpe, K., Robinson, K., Cohen, R., Barnett TM., Cohen, R., Masini, M. Prospective Assessment of the Impact of Obesity on Early Postoperative Outcomes of Cementless Total Knee Arthroplasty AAHKS 2017.
- Sinicrope BJ, Feher AW, Bhimani SJ, Smith LS, Harwin SF, Yakkanti MR, Malkani AL. Increased Survivorship of Cementless versus Cemented TKA in the Morbidly Obese. A Minimum 5-Year Follow-Up. J Arthroplasty. 2019 Feb;34(2):309-314. doi: 10.1016/j.arth.2018.10.016. Epub 2018 Oct 17. PMID: 30446183.
- Restrepo, S, Hozack, W, Smith E. Minimum five-year follow-up of a novel 3-D printed tibial baseplate for cementless total knee arthroplasty. Orthopaedic Proceedings, Vol. 102-B, No. SUPP\_9.
- 42. Firestein GS. Evolving concepts of rheumatoid arthritis. Nature. 2003;423(6937):356-361. doi:10.1038/ nature01661.
- Helmick CG, et al. Estimates of the Prevalence of Arthritis and Other Rheumatic Conditions in the United States. Part I. Arthritis Rheumatism. 2008;58(1):15–25.
- Patel, N., et.al. Outcomes of Cementless Total Knee Arthroplasty in Patients With Rheumatoid Arthritis. Othopedics, vol. 41, no. 2, 2018, pp.103-106.
- 45. Ryd et al. 1995 Ryd L, Albrektsson B E, Carlsson L, Dansgard F, Herberts P, Lindstrand A, Regner L, Toksvig-Larsen S. Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. J Bone Joint Surg Br 1995; 77(3): 377–83.
- Nilsson K et al. Evaluation of Micromotion in Cemented vs Uncemented Knee Arthroplasty in Osteoarthritis and Rheumatoid Arthritis. Journal of Arthroplasty. Vol 6. No 3. September 1991. 265-278.

- Bhimji et al. The effect of fixation design on micromotion of cementless tibial baseplates. ORS 2012. Poster 1977.
- 48. Stryker technical report: Report number RD-13-107. Effect of geometry on peg fixation strength. 2013.
- 49. Stryker tolerance analysis: Project number 92911. Triumph Tritanium Knee. D02521-1; 2013.
- 50. Sporer S, MacLean L, Burger A, Moric M. Evaluation of a 3D-printed total knee arthroplasty using radiostereometric analysis: assessment of highly porous biological fixation of the tibial baseplate and metal-backed patellar component. Bone Joint J. 2019 Jul;101-B(7\_Supple\_C):40-47. doi: 10.1302/0301-620X.101B7.BJJ-2018-1466.R1. PMID: 31256643.
- Pijls, BG, Plevier J, Nelissen, R. RSA migration of total knee replacements: A systematic review and metaanalysis. Acta Orthopaedica 2018; 89 (3): 320–328.
- 52. Dunbar, MJ et.al. Stable migration of peri-apatitecoated uncemented tibial components in a multicentre study. Bone Joint J 2017;99-B:1596–1602.
- Robinson JC, Pozen A, Tseng S, Bozic KJ. Variability in costs associated with total hip and knee replacement implants. J Bone Joint Surg Am. 2012 Sep 19;94(18):1693-8.
- Macario, A. What does one minute of operating room time cost? Journal of Clinical Anesthesia (2010) 22, 233–236.
- 55. Volpin A, Khan O, Haddad FS. Theater Cost Is £16/ Minute So What Are You Doing Just Standing There? J Arthroplasty. 2016 Jan;31(1):22-6. doi: 10.1016/j. arth.2015.08.008. Epub 2015 Aug 14.
- 56. Chen, A et. al. Cementless versus Cemented TKA: Shorter Operative Time and Similar Complications. Eastern Orthopedic Association 2016. New Orleans, LA.
- Lawrie CM, Schwabe M, Pierce A, Nunley RM, Barrack RL. The cost of implanting a cemented versus cementless total knee arthroplasty. Bone Joint J. 2019 Jul;101-B(7\_Supple\_C):61-63. doi: 10.1302/0301-620X.101B7.BJJ-2018-1470.R1. PMID: 31256655.
- 58. Hansen, EN, et.al. Routine use of antibiotic laden bone cement for primary total knee arthroplasty: impact on infecting microbial patterns and resistance profiles. J Arthroplasty. 2014 Jun;29(6):1123-7. doi: 10.1016/j. arth.2013.12.004. Epub 2013 Dec 10.

- Inabathula, A. et.al. Extended Oral Antibiotic Prophylaxis in High-Risk Patients Substantially Reduces Primary Total Hip and Knee Arthroplasty 90-Day Infection Rate. J Bone Joint Surg Am. 2018 Dec 19;100(24):2103-2109.
- Kallala, R., Anderson, P., Morris, S., Haddad, FS. The cost analysis of cemented versus cementless total hip replacement operations on the NHS. Bone Joint J 2013;95-B:874–6.
- Grau LC, Ong AC, Restrepo S, Griffiths SZ, Hozack WJ, Smith EB. Survivorship, Clinical and Radiographic Outcomes of a Novel Cementless Metal-Backed Patella Design. J Arthroplasty. 2021 Feb 16:S0883-5403(21)00171-6. doi: 10.1016/j.arth.2021.02.032. Epub ahead of print. PMID: 33676814.
- Harwin SF, DeGouveia W, Sodhi N, Gold PA, Garbarino LJ, Ehiorobo JO, Salem HS, Mont MA. Outcomes of Cementless-Backed Patellar Components. J Knee Surg. 2020 Sep;33(9):856-861. doi: 10.1055/s-0040-1710378. Epub 2020 May 29. PMID: 32483801.
- 63. Hasan S, van Hamersveld KT, Marang-van de Mheen PJ, Kaptein BL, Nelissen RGHH, Toksvig-Larsen S. Migration of a novel 3D-printed cementless versus a cemented total knee arthroplasty: two-year results of a randomized controlled trial using radiostereometric analysis. Bone Joint J. 2020 Aug;102-B(8):1016-1024. doi: 10.1302/0301-620X.102B8.BJJ-2020-0054.R1. PMID: 32731825.
- 64. Carlsson A, Björkman A, Besjakov J, Onsten I. Cemented tibial component fixation performs better than cementless fixation: a randomized radiostereometric study comparing porous-coated, hydroxyapatite-coated and cemented tibial components over 5 years. Acta Orthop. 2005;76(3):362–369.
- 65. Van Hamersveld KT, Marang-Van De Mheen PJ, Nelissen RGHH, ToksvigLarsen S. Peri-apatite coating decreases un-cemented tibial component migration: long-term RSA results of a randomized controlled trial and limitations of short-term results. Acta Orthop. 2018;89(4):425–430.
- 66. Henricson A, Linder L, Nilsson KG. A trabecular metal tibial component in total knee replacement in patients younger than 60 years: a two-year radiostereophotogrammetric analysis. J Bone Joint Surg Br. 2008;90-B(12):1585–1593Hansson U, Ryd L, Toksvig-Larsen S. A randomised RSA study of Peri-Apatite<sup>™</sup> HA coating of a total knee prosthesis. Knee. 2008;15(3):211–216.

- Hansson U, Ryd L, Toksvig-Larsen S. A randomised RSA study of Peri-Apatite HA coating of a total knee prosthesis. Knee. 2008 Jun;15(3):211-6. doi: 10.1016/j. knee.2008.01.013. Epub 2008 Mar 10. PMID: 18329882.
- 68. Bhowmik-Stoker, M., Nevelos J., Barrack R., Mont, M., Mahoney, O., Dunbar, M., Nam, D. Mid-term Performance of the First Mass Produced 3D Printed Cementless Knee in the United States as Reported in the American Joint Replacement Registry. The 2021 Members Meeting of The Knee Society. 9-10 September, Napa, CA.
- Bhowmik-Stoker, M., Nevelos, J., Barrack, R., Mont, M, Mahoney, M., Dunbar, M and Nam, D. Mid-term Performance of 28,257 Metal-Backed Patellae from the American Joint Replacement Registry (AJRR). [Poster session]. 2021 AAHKS Annual Meeting, 11-14 November 2021, Dallas, TX.
- 70. American Joint Replacement Registry. Annual Report 2021. https://connect.ajrr.net/2021-ajrr-annual-report.
- Stryker technical report: Report number RD-12-044. Tritanium patella static tensile bond strength of poly/ metal interface. 2013.

## Notes

# stryker

#### Joint replacement

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker's product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any of Stryker's products. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your sales representative if you have questions about the availability of products in your area.

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: AMagine, Peri-Apatite, SOMA, Stryker, Triathlon, Tritanium. All other trademarks are trademarks of their respective owners or holders.

TRITAN-WP-1\_Rev-3\_31892 Copyright © 2022 Stryker